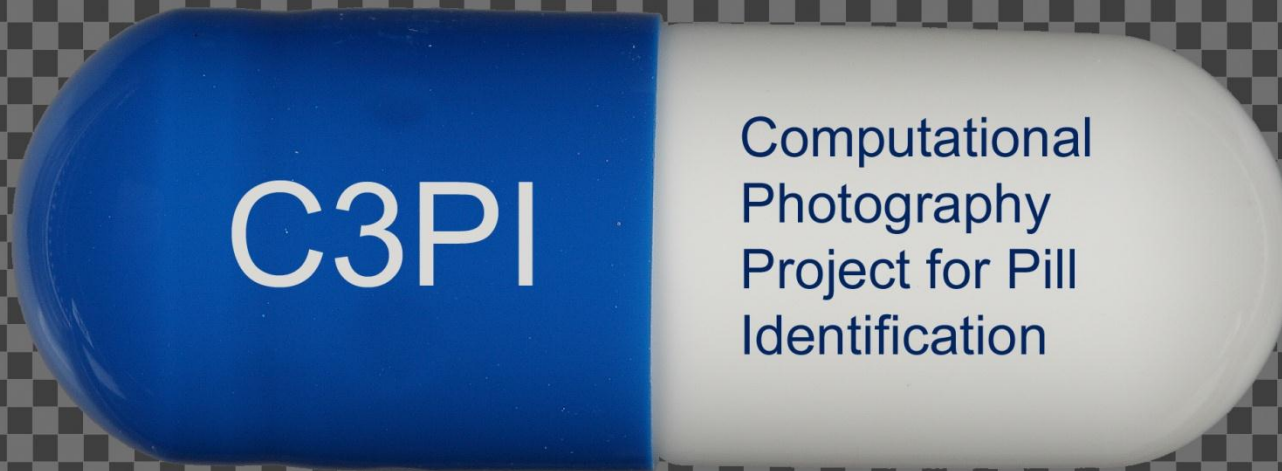


July 26, 2012

SPL Working Group Presentation



Pablo R. Perillan MD, PhD
pablo@medicosconsultants.com



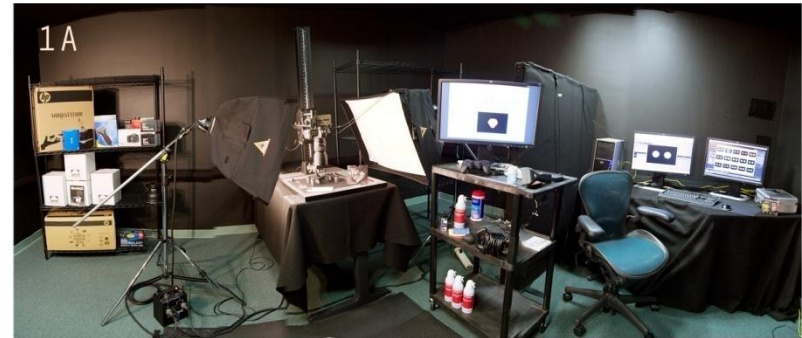
S P L	NDC: 00000-0000	DATE: 20091014	IMPRINT: C3PI
	SIZE: 10mm	SCORE: no score	COLOR: WHITE (Blue Opaque)
	COATING: N/A	SYMBOL: N/A	SHAPE: CAPSULE
	Office of High Performance Computing & Communications		Computational Photography Project for Pill Identification (C3PI)
CS: sRGB IEC61966-2.1		DPI: 2009	IMAGE DATE: 4th February 2011

Imaging Facilities, Oral Solid Dosage Formulation (OSDF) Supply

- ▶ **C3PI & SPLIMAGE Imaging Laboratories**
 - ▶ Locations: Rockville [FDA], Baltimore and Philadelphia [Medicos Consultants]
 - ▶ Light Controlled - 2,000+ sq. ft. facilities
- ▶ **FR Respondents and Direct Access to Pharmacy Supply and Wholesalers**
 - ▶ Federal Register Notice Respondents: Allergan, GSK, Bayer, and Teva
 - ▶ Epic Pharmacy Supply Partnership, McKesson and ANDANet Wholesale Distribution Access
 - ▶ Florida A&M University (FAMU)
 - ▶ Office of the Assistant Secretary for Preparedness and Response (ASPR)
- ▶ **High Performance Reference Rig**
 - ▶ 21.1MP, Full Frame SLR, Cross-Polarized Illumination Apparatus
 - ▶ High-Throughput, Calibrated and Specialized Macro-Photography Techniques
 - ▶ Automated Color and Size Calibration, OSDF Orientation
 - ▶ Content Management System Integration: Inventory Module, Imaging Controls & Image Processing Suite
- ▶ **Scalable and Flexible Test Rig for “Real World” Simulations**
 - ▶ 8+ types of Cameras (3MP – 15MP), Mobile Phones, WebCams, Consumer Grade Cameras, etc.
 - ▶ 10+ Light Sources (2800K – 6500K) Incandescent, Fluorescent & Solid-State (LED)
 - ▶ Direct, Indirect and Diffuser Modified
 - ▶ Manual and Computer Controlled Illumination
 - ▶ Flexible and Scalable Weighted Bayesian Distribution Sparse Matrix Acquisition Protocol

Imaging Laboratory at FDA Gaither Road Facility

- ▶ NLM Imaging Lab at FDA
2094 Gaither Road,
Rockville Maryland



C3PI: Community Pharmacy Partnership

- ▶ Epic Pharmacy Chain Partnership
- ▶ Suburban and Urban Locations
- ▶ Primary and Tertiary Care Distribution Centers



C3PI-SPLIMAGE: Reference Imaging Rig



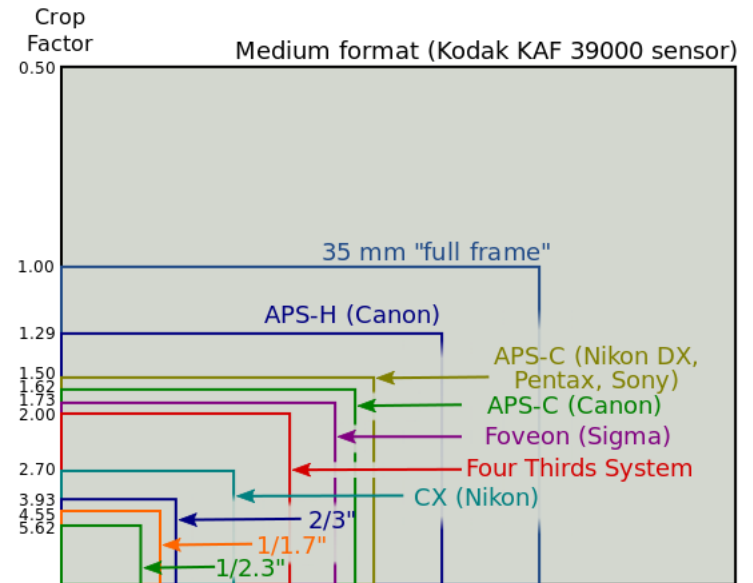
C3PI-SPLIMAGE: Reference Rig

- ▶ 21.1 MP Full-Frame SLR
- ▶ Remote Camera Controllers
- ▶ Macro-Calibration Slide
- ▶ Cross-Polarizer Apparatus
- ▶ Inline-NIST Color Calibration
- ▶ Whibal[®] & Kodak Gray Calibration
- ▶ Automated Sizing, Aspect and Specimen Registration
- ▶ Multiple Gobo Channels
- ▶ Floating Specimen Stage



C3PI-SPLIMAGE: Technical Considerations

- ▶ Sensor Sizes
- ▶ 35 mm “Full Frame”
- ▶ 21 Mega Pixel



C3PI-SPLIMAGE: Technical Considerations

- ▶ Macro Magnification
- ▶ Macro 100mm Lens

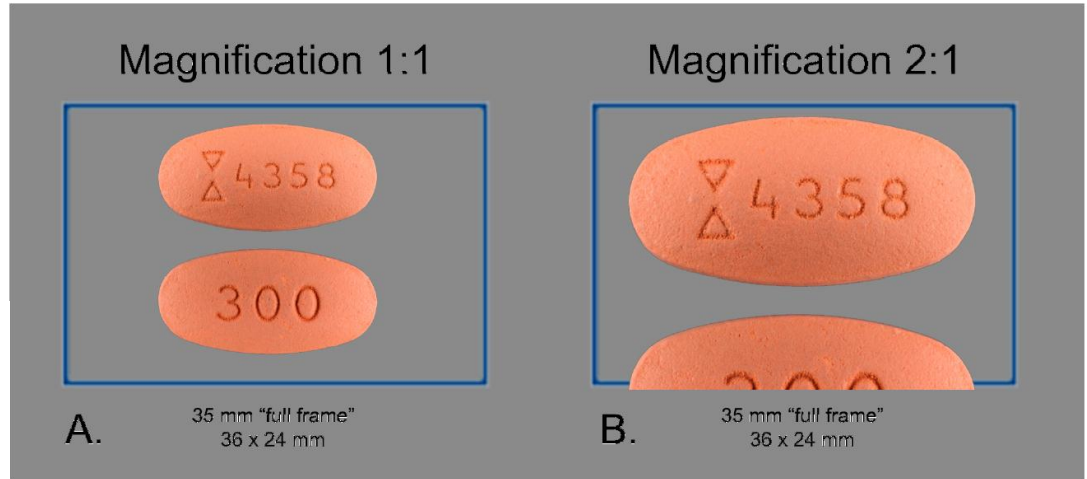
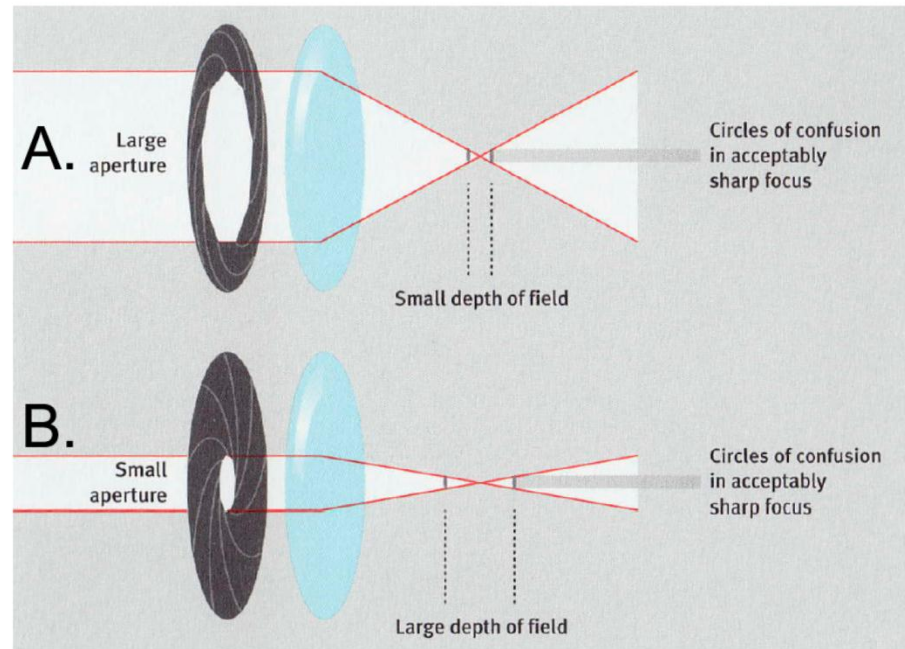
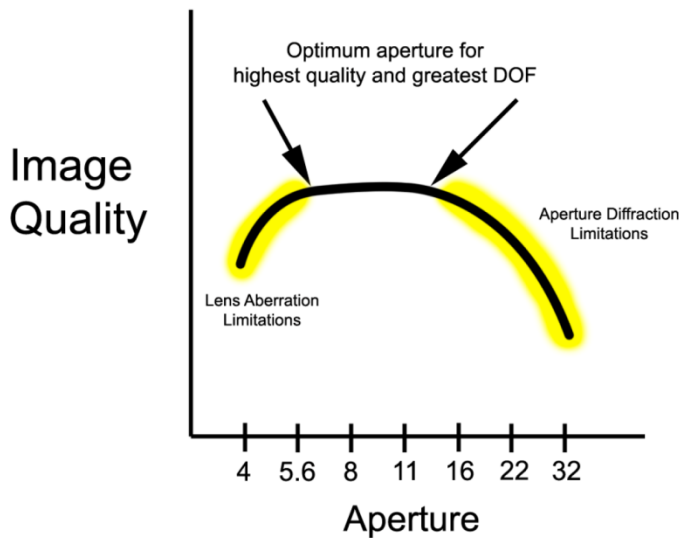


Figure 2 – Full-Frame (35mm: 36x24mm sensor) (A.) Magnification 1:1. Obverse and reverse sides of a typical SDF fit on a single imaging plane. (B.) Magnification 2:1. Typical SDF will not fit both obverse and reverse sides on a single 35mm imaging sensor exposure.

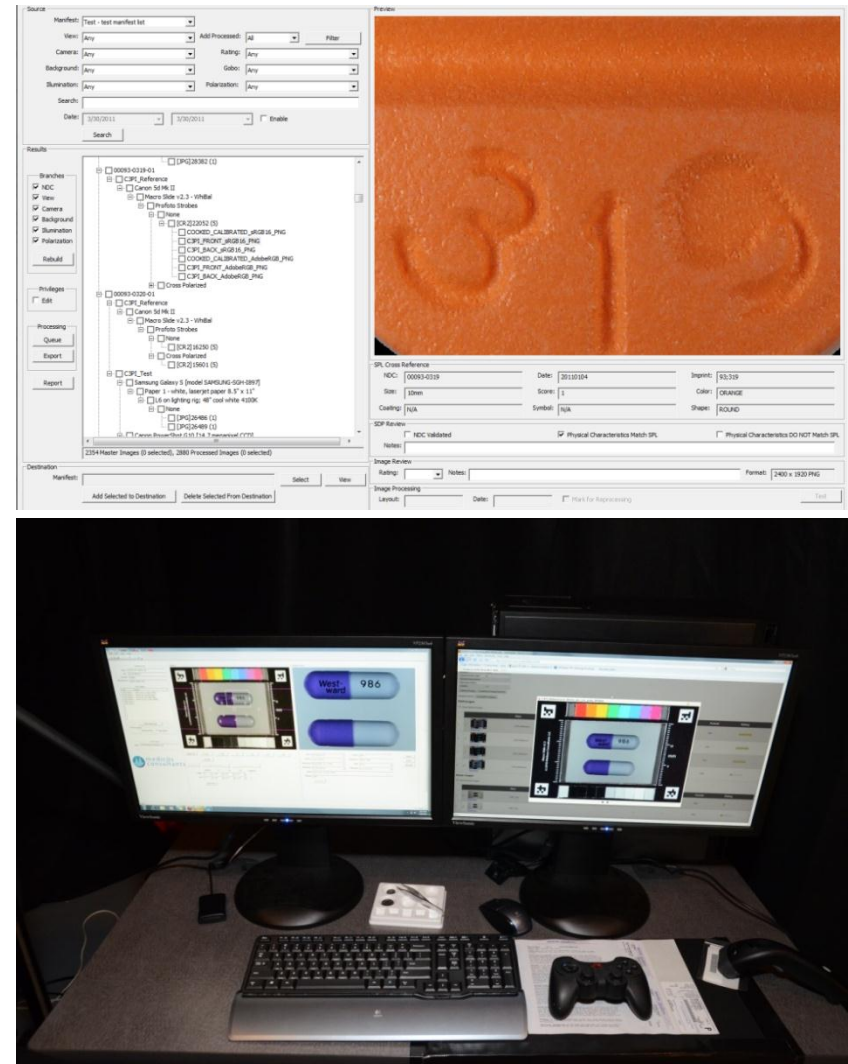
C3PI-SPLIMAGE: Technical Considerations

- ▶ Depth of Field
- ▶ Image Quality
- ▶ Illumination
- ▶ Sensor Noise



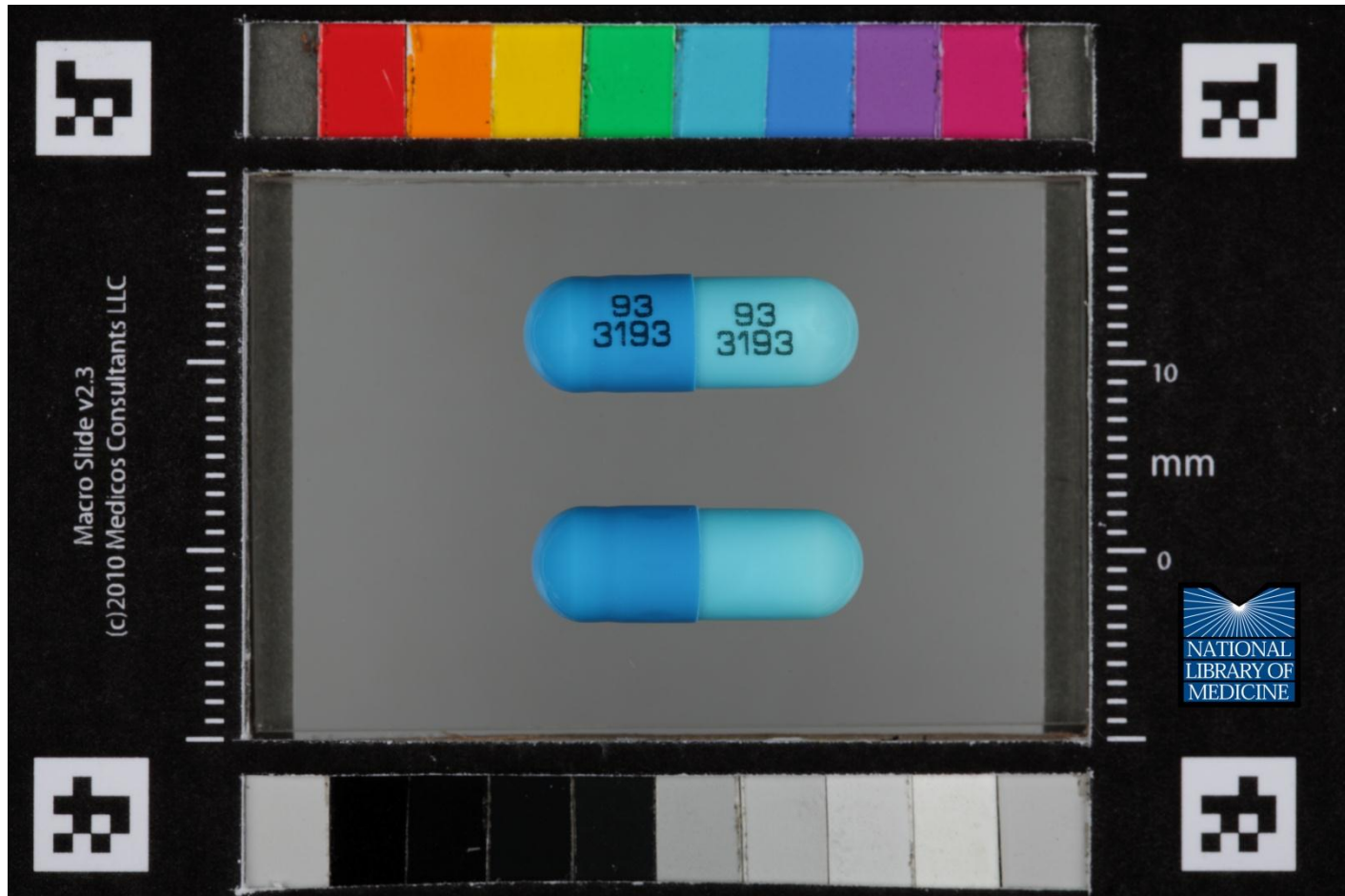
C3PI-SPLIMAGE: Imaging and Content Management System

- ▶ Current Archive Size:
 - ▶ 1,558 Solid Dosage Products
 - ▶ 19,485 Reference Images
 - ▶ 22,451 Test/Query Images
 - ▶ 1,558 HD Video Files
 - ▶ 687 SPLIMAGE Files
 - ▶ 44,271 Processed, Segmented Images & Files Delivered
 - ▶ Multiple Color Domain Spaces [Adobe RGB, Canon sRGB]
- ▶ Projected C3PI Archive (5YR):
 - ▶ 320,000 Image & Video Files
 - ▶ 14,000+ Solid Dosage Products
 - ▶ 15+ Terabytes of Image Data



C3PI: Reference Images

- ▶ RAW Images: sRGB Canon & Adobe RGB



C3PI: Reference Images

► Non-Polarized and Cross-Polarized Image Acquisition



Non-Polarized



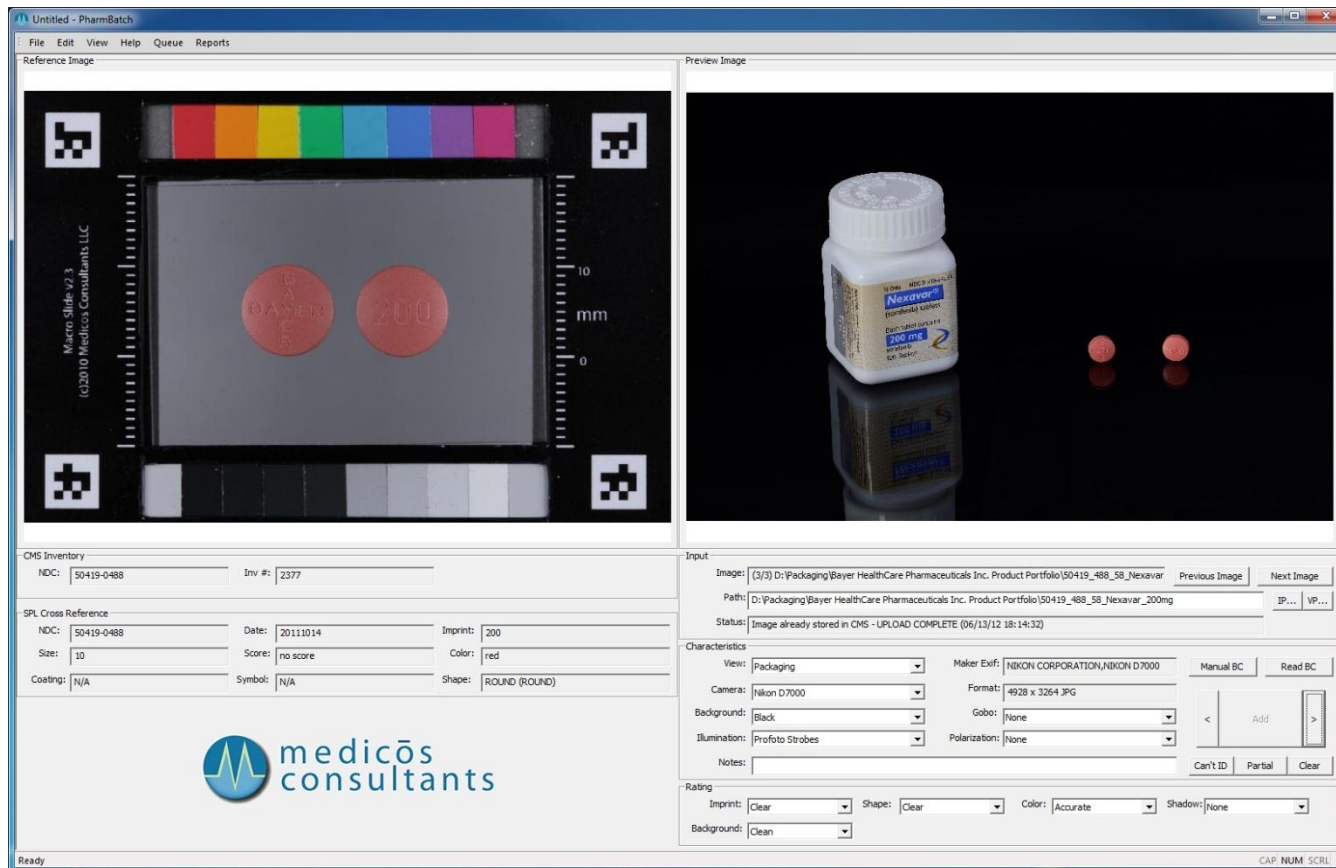
Cross-Polarized

Steps to Ensure that OSDFs are Properly Dispensed and Tracked through the C3PI/SPLIMAGE Workflow

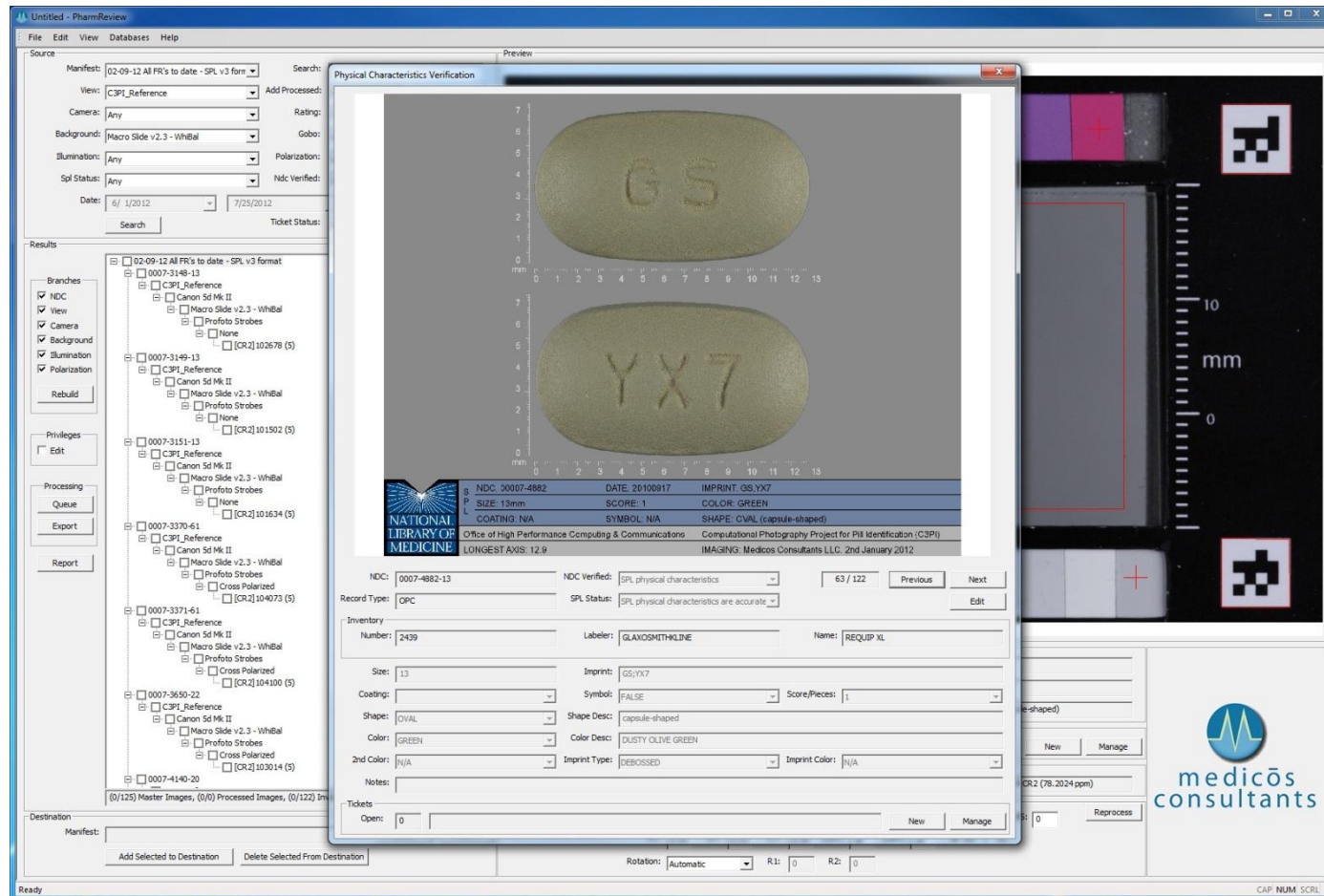
1. Targeted OSDF inventory is tagged for imaging by clinical staff using CMS Inventory Module: PharmFinder
2. Tagged OSDF samples are identified, examined, and prepared for dispensing by Licensed Pharmacy Technician
3. Prepared OSDF samples are examined, reviewed, and dispensed by Licensed Pharmacist
4. Dispensed OSDF inventory is barcoded and logged into the CMS Inventory Module
5. Barcoded OSDFs are then ready for imaging using the CMS ImagePharm Module
6. Reference Imaging of OSDFs tracked by barcode and NDC verification along with their unique inventory IDs at each step.
7. FR Notice Responders Product Packaging is Imaged to Provide Another Form of OSDF Validation

Steps to Ensure that OSDFs are Properly Dispensed and Tracked through the C3PI/SPLIMAGE Workflow

FR Notice Responders Product Packaging is Imaged to Provide Another Form of OSDF Validation



Steps to Ensure that OSDFs are Properly Dispensed and Tracked through the C3PI/SPLIMAGE Workflow



Inventory Control Details

NDC

Unique Inventory Identifier (Unique ID)

Labeler Name Displayed on Packaging

Product Name

Dose Size

Product Source

Lot # and/or Dispensing Tracking Number

Expiry Date

Storage Location

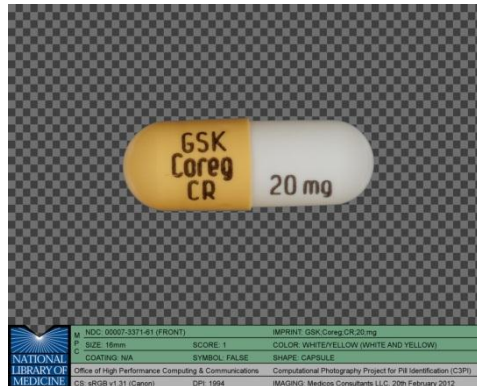
Reference Imaging Workflow

1. RAW Images Are Captured Directly Into the Imaging CMS Module ImagePharm
2. All Camera Controls are Wirelessly Controlled via ImagePharm Camera Controller
3. OSDF Samples Are Aligned Perpendicular to the Camera Lens
4. Various Combinations of Advanced Macro Techniques May be Employed (e.g. Goboes and Specialized Reflectors)
5. Reference Images are Shot Against a Macro Calibration Card
6. Use of Non-Polarized and Cross-Polarized Illumination
7. Various Backgrounds Used to Facilitate Product Segmentation
8. OSDF RAW Images Are Automatically Linked Into the Appropriate OSDF Inventory Container
9. Exact Imaging Conditions Are Also Captured Along With Each Image



C3PI: Reference Images

▶ Segmented Composed C3PI OHPCC



▶ Other C3PI Image Uses:

- ▶ FDA SPLIMAGE
- ▶ DailyMed, PubMed Health, Medline Plus Drugs, Herbs & Supplements, Medline Plus Connect (NCBI), Pillbox, etc.
- ▶ Imaging Research
- ▶ Public Interest and Commercial Uses

Quality Control Opportunities for Sponsors and Vendors

- ▶ Validated Color Mapping to FDA SPLIMAGE Color Selections
- ▶ Validated Sizing of OSDFs to within 0.1mm
- ▶ Validated Shape Categorization
- ▶ GMP Support for Testing of Batch to Batch Variability
- ▶ Novel and Automated Technologies for Product Authentication
- ▶ Integrated Workflow Support for Sponsors and Vendors

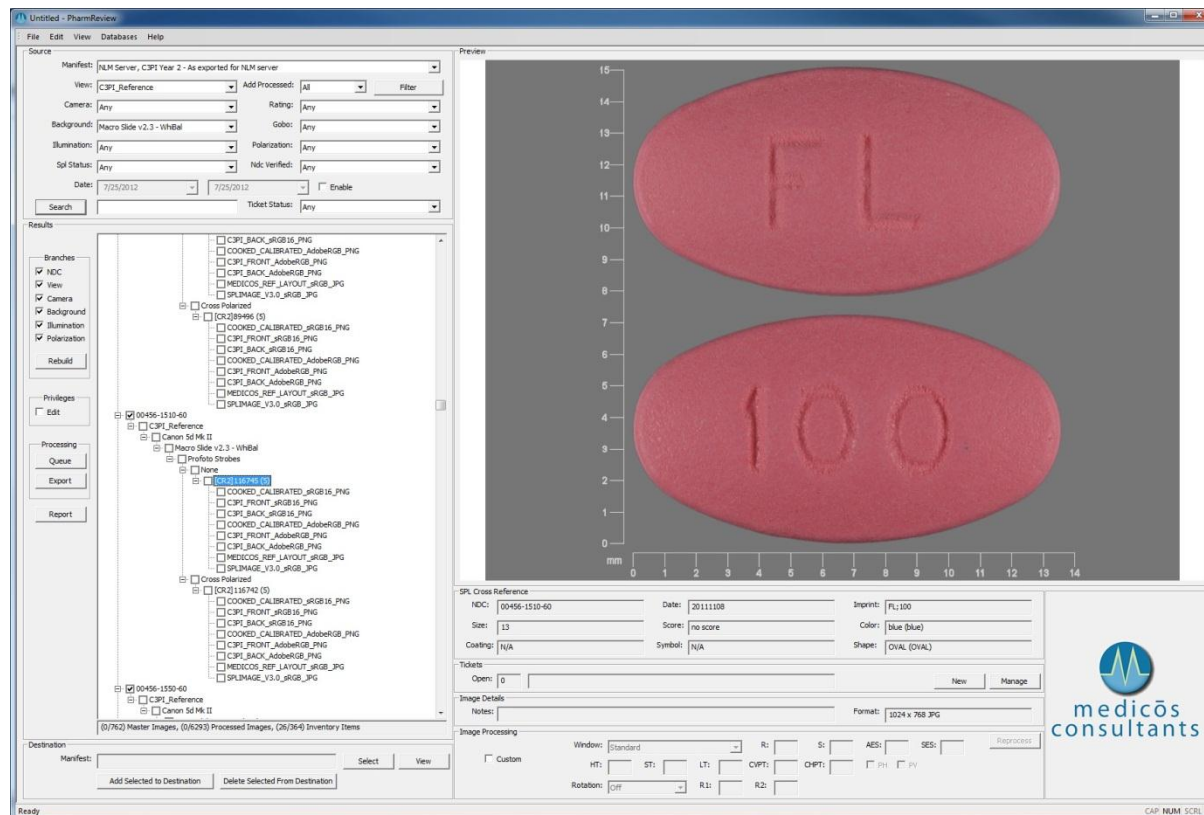


SPLIMAGE Files



SPLIMAGE Data Inconsistencies

- ▶ Size, Shape, Color & Imprint Inconsistencies
- ▶ Example: Color filed as “blue (blue)”

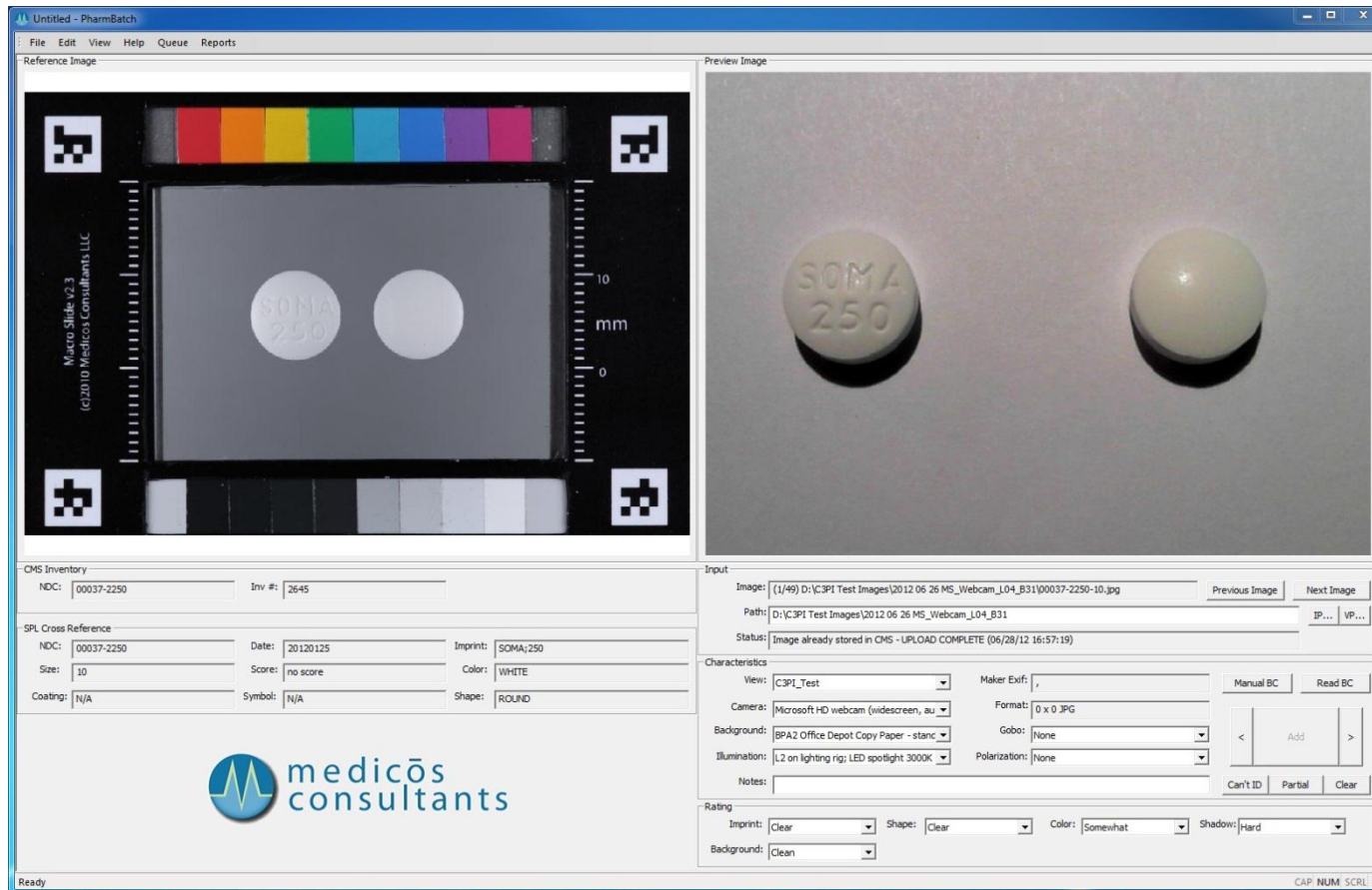


C3PI: Test/Query Imaging Rig

- ▶ 7+ Illumination Sources
 - ▶ 2800K to 6500K
 - ▶ Fluorescent
 - ▶ Incandescent
 - ▶ LED
 - ▶ CFC
 - ▶ Direct, Indirect & Diffusion Filter
- ▶ 8+ Camera Types
 - ▶ 3MP to 15MP Sensors
 - ▶ Mobile Phones
 - ▶ Consumer Grade Cameras
 - ▶ Web Cameras
 - ▶ Tethered and Independent Camera Support
- ▶ 30+ Background Types
- ▶ HD Video Capture



C3PI: Test/Query Images



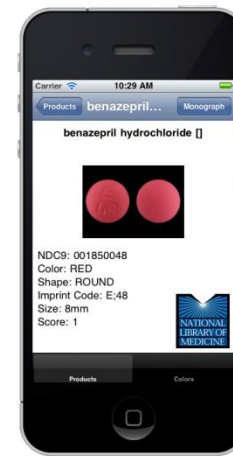
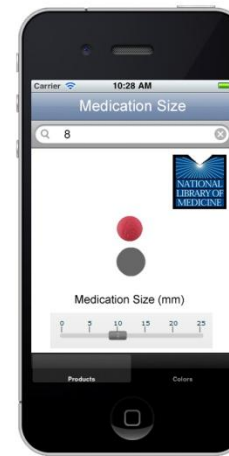
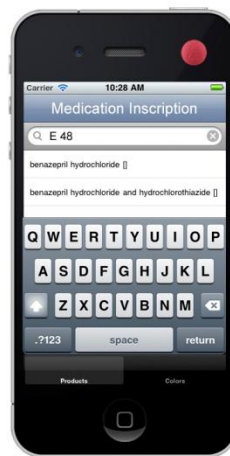
C3PI: Test/Query Images

- ▶ n-Permutations of: Illumination, Backgrounds, Rotations, Compositions, Image Sensors, Quality Ratings
- ▶ Weighted Bayesian Distribution Sparse Matrix



C3PI: Product Identification and Mobile Research Framework

- ▶ Image Recognition Research Support
- ▶ Mobile Application Framework
- ▶ Clinical Application Development for Community Outreach
 - ▶ e.g. UMMS and Institute of Human Virology
 - ▶ DailyMedPlus – NLM Mobile Application Finalist



Medicos Consultants

Pablo R. Perillan MD, PhD

pablo@medicosconsultants.com

Washington D.C. - Baltimore – Philadelphia